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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,439	03/18/2005	Gianluca Civenni	1-32642A/FMI	4298

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NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

HALVORSON, MARK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/528,439

Applicant(s)

CIVENNI ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/30/2005; 1/23/2006</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-10 17-19 in the reply filed on August 8, 2006 is acknowledged. Applicant's election of a Wnt1 antagonist is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-16, 20-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Upon review and reconsideration, the species election of the various combinations of species in claims 17-19 is withdrawn and the search is expanded to other species.

Claims 1-10, 17-19 are under prosecution.

### ***Specification***

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 1. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Claim Objections***

3. Claims 7-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. See MPEP § 608.01(n). Claims 8 and 9 depend on claim 7, a multiple dependent claim. Claim 7 depends on claim 4, a multiple dependent claim. To facilitate compact prosecution, claims 7 and 8 have been interpreted to only depend on the preceding claims, claims 6 and 7, respectively. However, this does not obviate the need for Applicant to amend claims 4, 7 or 8.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Rhee et al (US Patent Application Publication 20040203003, published Oct 14, 2004,

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priority filing date May 1, 2001) as evidenced by Ford et al. (Head and Neck , 2003, 25:67-73).

Claims 1-8 and 10 are drawn to a method for inhibiting EGF receptor signaling comprising contacting a cell having EGF receptors and Frizzled (Fz) at the cell surface with a Wnt1 antagonist, wherein the antagonist is an antibody that binds to Wnt1, wherein the antagonist is a antibody that binds to Fz, wherein the antagonist is sFRP, wherein the cell is an epithelial cell, wherein the cell is a solid tumor cell.

Rhee et al discloses that antibodies to Wnt1, antibodies to Fz, and sFRP1 had an inhibitory effect on three Head and Neck squamous carcinoma cell lines (HNSCC) that express Fz at the cell surface. Rhee does not specifically disclose that the HNSCC lines express ErbB1. However, as evidenced by Ford et al, who discloses that ErbB1 is expressed on most cell types especially those of ectodermal origin. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

5. Claims 17-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Schroeder et al (J Biol Chem, Jne 21, 2002, 277:22692-22698).

Claims 17-19 are drawn to a kit comprising Wnt, and Fz, and a means of detecting ErbB signaling, wherein said means of detecting ErbB signalling is an antibody, wherein the antibody comprises a detectable tag or label.

Schroeder et al disclose a cell expressing Wnt (see Abstract) and demonstrate signaling through ErbB (page 22694, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph to page 22695, 1<sup>st</sup> column, 1<sup>st</sup> paragraph). Detection of signaling through ErbB was accomplished using a labeled anti-phosphotyrosine antibody (Fig. 3).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al as applied to claims 1-8 and 10 above, and further in view of Wong et al (J Pathol, 2002, 196:145-153).

Claim 9 is drawn to a method for inhibiting EGF receptor signaling comprising contacting a cell having EGF receptors and Frizzled at the cell surface with a Wnt1 antagonist, the cell is a breast cancer cell.

Rhee et al is described supra.

Rhee does not disclose a breast cancer cell.

Wong et al disclose expression of Fz and Wnt in invasive breast cancer cell (see Abstract). Furthermore, claim 9 says that breast cancer cells inherently have EGF and Fz receptors at the cell surface.

One of ordinary skill in the art would have been motivated to apply Wong et al's teaching of Wnt expression on breast cancer cells to Rhee et al's teaching of using a Wnt antagonist in cancer because Wong et al state that significant of the Frp-Wnt signaling pathway in the development of breast cancer (page 153, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph). Thus it would have been prima facie obvious to one skilled in the art to have combined Rhee et al's teaching of using a Wnt antagonist with Wong et al disclosure of Wnt expression on breast cancer cell.

7. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al as applied to the species, Wnt and Fz.

Claims 17-19 are interpreted as being drawn to a kit comprising Wnt, and Fz, and a means of detecting ErbB signaling, wherein said means of detecting ErbB signalling is an antibody, wherein the antibody comprises a detectable tag or label.

Wong et al has been described supra.

Wong et al does not specifically disclose Fz. However, Wong et al states that binding of Wnt to Fz results in inactivation of an enzyme that indirectly results in the transcription of protooncogenes (page 22692, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph).

It would have been prima facie obvious to because activation a cell requires signaling.

### ***Summary***

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.




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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER